



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/073,766	03/28/2011	Bo U. Curry	20100176-02	8505

22878 7590 04/14/2017
Agilent Technologies, Inc. in care of:
CPA Global
P. O. Box 52050
Minneapolis, MN 55402

EXAMINER

ZEMAN, MARY K

ART UNIT	PAPER NUMBER
----------	--------------

1631

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/14/2017

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com
Agilentdocketing@cpaglobal.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BO U. CURRY and NICHOLAS M. SAMPAS¹

Appeal 2016-006071
Application 13/073,766
Technology Center 1600

Before FRANCISCO C. PRATS, TAWEN CHANG,
and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to analyzing data related to single polynucleotide polymorphisms, which have been rejected as being directed to non-statutory subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ Appellants identify the real party in interest as Agilent Technologies, Inc. Br. 3.

STATEMENT OF THE CASE

Single nucleotide polymorphisms (“SNPs”) are single base pair changes that occur in DNA and confer genetic differences between individuals. Spec. 1, ll. 7–9. “Methods for the determination of SNP alleles and copy number measurements are important to the research community for the diagnosis of disease, especially in cytogenetics and cancer.” *Id.* at 1, ll. 14–16.

Claims 1–20 are on appeal. Claim 1 is the sole independent claim and reads as follows:

1. A method of sample analysis, comprising:
 - a) obtaining a plurality of ratios indicating which alleles of a plurality of single nucleotide polymorphisms (SNPs) are present in diploid regions of a test genome from a test sample and a reference genome from a reference sample;
 - b) calculating a plurality of probability distribution functions that fit said plurality of ratios; and
 - c) estimating the allele-specific copy number of a SNP of said test genome using said plurality of probability distribution functions.

Claims 1–20 stand rejected under 35 U.S.C. § 101 as directed to patent ineligible subject matter.

DISCUSSION

Issue

Then issue is whether a preponderance of evidence supports the Examiner’s conclusion that claims 1–20 are directed to patent ineligible subject matter.

The Examiner finds that the claims are directed to “the abstract idea of analyzing genetic data, wherein [the] information is received regarding a test

genome and a reference genome, compared using computer system elements and calculations, and a characteristic of the test genome is determined.”

Final Act. 2. The Examiner finds that each of the steps is directed to an abstract idea and, therefore, is patent ineligible. *Id.* The Examiner also finds that the claims are directed to a second exception to patentable subject matter, a natural phenomenon. *Id.* at 2–3. The Examiner finds that the “presence of any particular genetic variant in a test genome relates to a natural principle.” *Id.* at 3. The Examiner finds that the claims do not recite any additional limitations which rise to the level of significantly more than the judicial exceptions. *Id.* at 3–4.

Appellants contend that the claims are directed to patentable subject matter because they are limited to a particular practical application. Br. 4. Appellants argue that the claimed method is not a familiar part of the conscious process that can be done in one’s head. *Id.* at 5. Appellants also argue that the claims are directed to a method where the data is transformed to provide new information. *Id.* at 6. Appellants argue that the claims are not directed to a natural law and that the Examiner has not offered any evidence that the additional limitations are not sufficient to amount to significantly more than the judicial exception. *Id.* at 7. Appellants conclude by arguing that the claims do not unduly pre-empt other methods of performing the analysis. *Id.*

Analysis

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the

record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Appellants do not persuade us that a preponderance of the evidence fails to support the Examiner's conclusion that the rejected claims recite subject matter ineligible for patenting under 35 U.S.C. § 101.

35 U.S.C. § 101 states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

The Supreme Court has “long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014).

Our reviewing court has summarized the Supreme Court’s two-part test for distinguishing between claims to patent-ineligible exceptions, and claims to patent-eligible applications of those exceptions, as follows:

Step one asks whether the claim is “directed to one of [the] patent-ineligible concepts.” [*Alice*, 134 S. Ct. at 2354]. If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, “the additional elements ‘transform the nature of the claim’ into a patent-eligible application.” *Id.* (quoting *Mayo [Collaborative Services v. Prometheus Labs, Inc.]*, 132 S. Ct. 1289, 1297 (2012))).

Step two is described “as a search for an ‘inventive concept.’” *Id.* (quoting *Mayo*, 132 S. Ct. at 1294). At step two, more is required than “well-understood, routine, conventional activity already engaged in by the scientific community,” which fails to transform the claim into “significantly more than a

patent upon the” ineligible concept itself. *Mayo*, 132 S. Ct. at 1298, 1294.

Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (paragraphing added).

In the present case, claim 1 recites the steps of obtaining data from a sample, performing calculations using the data, and making estimations relating to the sample based on the calculations. The claims fall within the category of mathematical relationships which renders them patent ineligible. “Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible.” *Digitech Image Techs., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014).

As to part two of the Supreme Court’s test, claim 1 does not recite any additional steps or limitations which transform the claim into something significantly more than the judicial exception.

We, therefore, agree with the Examiner that, under the Supreme Court’s two-part test, claim 1 recites subject matter ineligible for patenting under § 101.

Appellants’ arguments do not persuade us to the contrary.

Appellants contend that the claimed method is directed to a particular application of the data. Br. 4. However, as the Examiner has pointed out, the claims do not recite any particular application of the method. Ans. 11.

Appellants argue that the claimed method transforms data. Br. 6. We agree with the Examiner that the claims are directed to manipulation of data and do not transform matter or reduce an article to a different state or thing. Ans. 12. The claimed method only uses existing algorithms to manipulate

data to generate additional information. As such, the claims are directed to patent ineligible subject matter. *Digitech Image Techs.*, 758 F.3d at 1351.

We are not persuaded by Appellants' argument that the calculations required for each step are not ones that can be performed in one's head. Br. 5. We agree with the Examiner that, while the steps may be tedious, that does not mean that they are not mental steps. Ans. 13.

Appellants' argument that the claims do not preclude using other methods to determine the number of SNPs in the test genome indicates that the method is patentable is also not persuasive. Br. 7. Our reviewing court has expressly rejected similar contentions regarding preemption, stating that a patentee's "attempt to limit the breadth of the claims by showing alternative uses . . . outside of the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). The court explained that, "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. . . . Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework . . . preemption concerns are fully addressed and made moot." *Id.*

In the present case, as discussed above, Appellants' claim 1 is limited to patented ineligible subject matter under the *Mayo* framework. Thus, that alternatives outside the claims are not preempted does not demonstrate patent eligibility.

We are unpersuaded by Appellants' argument that the Examiner has failed to produce any evidence to support the proposition that the claims do not present something substantially more than the judicial exceptions. Br. 7.

As the Examiner points out, the Guidance of 30 July 2015² states that, once the Examiner identifies and explains the reasons why a claim is ineligible, “the burden shifts to the Applicant to either amend the claim or make a showing of why the claim is eligible for protection’ (footnote 15, Section IV). It is maintained that Appellant[s] did not present evidence of such a showing herein and provided opinion arguments at why the claims satisfy the requirement under 35 [U.S.C. §] 101.” Ans. 14.

In sum, for the reasons discussed, Appellants do not persuade us that a preponderance of the evidence fails to support the Examiner’s conclusion that Appellants’ claim 1 is patent-ineligible under § 101. Accordingly, we affirm the Examiner’s rejection of claim 1 on that ground. Because they were not argued separately, claims 2–20 fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm the rejection under 35 U.S.C. § 101.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

² USPTO, July 2015 Update: Subject Matter Eligibility (July 30, 2015), <https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf>